REMARKS

The Office Action mailed November 20, 2002 has been received and reviewed. Claims 1, 3, 5-7, 11, 13, 14, 73-86 and 96 are pending in the application. All claims stand rejected. Claims 22 and 88-96 have been withdrawn from consideration as assertedly being drawn to a non-elected invention. Claims 1, 3, 5-7, 11, 13, 14, 73-86 and 97 are pending and under consideration in the application. Claims 1, 6, 7, 11, 73, 81-86 and renumbered claim 96 have been amended and new claims 97-105 have been added as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Correction of Spelling of Inventor's Name

The name of the first named inventor was misspelled on the first page of the specification. The name Hateboer included an extra "t." The name has been corrected as set forth herein. The declaration as filed included the proper spelling of Hateboer. In accordance with M.P.E.P. § 201.03, applicants are notifying the Office of the discovery of the typographical error. (*See*, M.P.E.P. § 201.03, 200-5).

Drawings

The drawings were objected to by the draftsman as assertedly including unacceptable margins, lines that were not well defined and poor numbers, letters or reference characters. Submitted herewith is a Transmittal of Formal Drawings with formal drawings that correct the informalities. Withdrawal of the objections is thus requested.

Objections to Claims

The Office noted that the numbering of the claims was not in accordance with 37 C.F.R. § 1.126 and claims 88-97 were renumbered to claims 87-96. Renumbered claim 96 is currently pending in the application and will be referred to as such.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1, 5, 6, 7, 11, 13, 14, 73-75, 76 and 96 were rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement for a method using a functional homologue, fragment or derivative of adenovirus E1A protein. At least partially in view of the amendments to claims 1, 6, 7 and 96, applicants respectfully traverse the rejections.

Specifically, it was thought that the specification, while being enabling for the E1A protein, was non-enabling for functional homologues, fragments or derivatives of the E1A protein. Although applicants do not agree with the Office that the claims are not enabled, for the sake of expedited prosecution, the phrase "or a functional homologue, fragment or derivative thereof" has been removed from claims 1, 6, 7 and 96. Applicants disagree since it is known by those skilled in the art that some amino acid substitutions will not change the function of a protein, *e.g.*, a conservative amino acid substitution in a protein. Thus, proteins with the equivalent function of the claimed adenoviral E1 protein are considered to be within the scope of the pending claims.

Claims 5, 11, 13, 14, 73-75 and 76 are enabled as depending from amended claims 1, 6 or 7.

Accordingly, reconsideration and withdrawal of the enablement rejections of claims 1, 5, 6, 7, 11, 13, 14, 73-75, 76 and 96 are respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 3, 5, 7, 11, 13, 14, 73 and 76-86 were rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse the rejections at least partly in view of the amendments to claims 1, 11, 73 and 82-86.

Although applicants do no agree that the claims are indefinite, independent claim 1 has amended to recite in part "which eukaryotic cell further does not comprise a sequence encoding a structural adenoviral protein in its genome" for the sake of expedited prosecution. As amended, independent claim 1 and claims 3, 5, 7, 11, 13, 14, 76-79, 81-84 and 86 depending therefrom are definite.

Claims 7, 11, 73 and 81-86 were thought to be indefinite for use of the phrase "and/or." For the sake of expedited prosecution, claims 11 and 73 have been amended to remove "and/" and to recite "or a combination thereof" and claims 82-86 have been amended to remove "and/." Accordingly, claims 8, 11, 73 and 81-86 are definite.

With further regard to claim 81, it was though to lack antecedent basis. To expedite prosecution, the phrase "human recombinant protein" has been replaced with the phrase "proteinaceous substance" which is supported by claim 7. Accordingly, claim 81 should be definite.

The amendments to claims 1, 11, 73 and 82-86 are cosmetic, *i.e.*, the amendments clarify that which applicants regard as their invention, and should not be construed as narrowing the scope of the claims.

Regarding claim 80, applicants respectfully submit that it should not have been rejected as being indefinite since claim 80 depends from independent claim 6, which was not deemed indefinite, and does not contain language deemed as indefinite.

In view of the amendments and remarks presented herein, reconsideration and withdrawal of the indefinite rejections of claims 1, 3, 5, 7, 11, 13, 14, 73 and 76-86 are respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 1, 3, 5, 6, 7, 11, 13, 14, 73-76 and 96 were rejected under 35 U.S.C. § 102 as assertedly being anticipated by Setoguchi et al. (Blood, vol. 84 (9), pp. 2946-2953, November 1, 1994). Applicants respectfully traverse the rejections as set forth herein.

The claims are not anticipated since Setoguchi et al. does not teach each and every element of the pending claims. Independent claims 1 and 6 require providing a cell having a sequence encoding at least one adenoviral E1 protein in the cell's genome and harvesting a proteinaceous substance or a recombinant protein from the cell. The construct (AdMLP.Epo) of Setoguchi et al. has the majority of E1 deleted (*See*, Setoguchi et al., Abstract) and the genomes of the cells into which the construct is transferred (*e.g.*, COS-7 cells) for the production of EPO

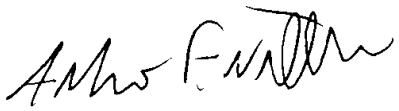
do not include sequences encoding at least one adenoviral E1 protein. (*See, Id.* at page 2947). Accordingly, the claims are not anticipated by Setoguchi et al.

Reconsideration and withdrawal of the anticipation rejections of claims 1, 3, 5, 6, 7, 11, 13, 14, 73-76 and 96 are, thus, respectfully requested.

CONCLUSION

If questions exist after consideration of the foregoing, the Office is kindly requested to contact the applicants' representative at the address or telephone number below.

Respectfully submitted,



Andrew F. Nilles
Registration No. 47,825
Attorney for Applicants
TRASKBRITT, PC
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

Date: January 30, 2003
AFN/afn

Enclosures: Marked up version of specification showing changes made
Marked up version of claims showing changes made
Transmittal of Formal Drawings

Document in ProLaw

MARKED UP VERSION OF SPECIFICATION SHOWING CHANGES MADE

Guus [Hatteboer] Hateboer
Karine Cornelia Verhulst
Govert Johan Schouten
Alphonsus Gerardus Cornelis Maria Uytdehaag
Abraham Bout

MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE

1. (Amended) A method for producing at least one proteinaceous substance in a eukaryotic cell, said method comprising:

providing a eukaryotic cell having a nucleic acid sequence in the eukaryotic cell's genome, said nucleic acid sequence encoding at least one adenoviral E1 protein [or a functional homologue, fragment or derivative thereof], which eukaryotic cell further does not comprise a sequence encoding [encode] a structural adenoviral protein in its genome [or a sequence integrated therein];

providing said eukaryotic cell with a gene encoding a recombinant proteinaceous substance;

culturing said eukaryotic cell in a suitable medium; and

harvesting at least one proteinaceous substance from said eukaryotic cell, said suitable medium, or both said eukaryotic cell and said medium.

6. (Amended) A method for producing at least one human recombinant protein in a cell, said method comprising:

providing a [eukaryotic] human cell [which is human], with a gene encoding a human recombinant protein, wherein said human cell has in its genome [having] a sequence encoding at least one adenoviral E1 protein [or a functional derivative, homologue or fragment thereof in the human cell's genome which] and wherein said human cell further does not produce structural adenoviral proteins;

culturing said human cell in a suitable medium; and

harvesting the human recombinant protein from the human cell, the suitable medium, or both said human cell and said medium.

7. (Thrice amended) The method according to claim 1, wherein said at least one adenoviral E1 protein comprises an E1A protein [or a functional homologue, fragment and/or derivative thereof].

11. (Thrice amended) The method according to claim 1, wherein said proteinaceous substance is a protein that undergoes post-translational [and/]or peri-translational modification, or a combination thereof.

73. (Amended) The method according to claim 6, wherein said human recombinant protein is a protein that undergoes post-translational [and/]or peri-translational modification, or a combination thereof.

81. (Amended) The method according to claim 7, wherein said [human recombinant protein] proteinaceous substance comprises a viral protein other than an adenoviral protein.

82. (Amended) The method according to claim 77, where said viral protein is selected from the group consisting of: an influenza virus neuramidase [and/]or a hemagglutinin; an enterovirus protein or a functional equivalent thereof; a herpes virus protein or a functional equivalent thereof; an orthomyxovirus protein; a retrovirus, a parvovirus or a popavovirus protein; a rotavirus or a coronavirus protein; a togavirus protein, rubella virus protein or an Eastern-, Western-, or Venezuelan equine encephalomyelitis virus protein; a hepatitis causing virus protein, a hepatitis A protein, or a hepatitis B virus protein; and a pestivirus protein, such as hog cholera virus protein or a rhabdovirus protein, such as a rabies virus protein.

83. (Amended) The method according to claim 78, where said viral protein is selected from the group consisting of: an influenza virus neuramidase [and/]or a hemagglutinin; an enterovirus protein or a functional equivalent thereof; a herpes virus protein or a functional equivalent thereof; an orthomyxovirus protein; a retrovirus, a parvovirus or a popavovirus protein; a rotavirus or a coronavirus protein; a togavirus protein, rubella virus protein or an Eastern-, Western-, or Venezuelan equine encephalomyelitis virus protein; a hepatitis causing virus protein, a hepatitis A protein, or a hepatitis B virus protein; and a pestivirus protein, such as hog cholera virus protein or a rhabdovirus protein, such as a rabies virus protein.

84. (Amended) The method according to claim 79, where said viral protein is selected from the group consisting of: an influenza virus neuramidase [and/]or a hemagglutinin; an enterovirus protein or a functional equivalent thereof; a herpes virus protein or a functional equivalent thereof; an orthomyxovirus protein; a retrovirus, a parvovirus or a popavovirus protein; a rotavirus or a coronavirus protein; a togavirus protein, rubella virus protein or an Eastern-, Western-, or Venezuelan equine encephalomyelitis virus protein; a hepatitis causing virus protein, a hepatitis A protein, or a hepatitis B virus protein; and a pestivirus protein, such as hog cholera virus protein or a rhabdovirus protein, such as a rabies virus protein.

85. (Amended) The method according to claim 80, where said viral protein is selected from the group consisting of: an influenza virus neuramidase [and/]or a hemagglutinin; an enterovirus protein or a functional equivalent thereof; a herpes virus protein or a functional equivalent thereof; an orthomyxovirus protein; a retrovirus, a parvovirus or a popavovirus protein; a rotavirus or a coronavirus protein; a togavirus protein, rubella virus protein or an Eastern-, Western-, or Venezuelan equine encephalomyelitis virus protein; a hepatitis causing virus protein, a hepatitis A protein, or a hepatitis B virus protein; and a pestivirus protein, such as hog cholera virus protein or a rhabdovirus protein, such as a rabies virus protein.

86. (Amended) The method according to claim 81, where said viral protein is selected from the group consisting of: an influenza virus neuramidase [and/]or a hemagglutinin; an enterovirus protein or a functional equivalent thereof; a herpes virus protein or a functional equivalent thereof; an orthomyxovirus protein; a retrovirus, a parvovirus or a popavovirus protein; a rotavirus or a coronavirus protein; a togavirus protein, rubella virus protein or an Eastern-, Western-, or Venezuelan equine encephalomyelitis virus protein; a hepatitis causing virus protein, a hepatitis A protein, or a hepatitis B virus protein; and a pestivirus protein, such as hog cholera virus protein or a rhabdovirus protein, such as a rabies virus protein.

96. (Amended) The method according to claim 6, wherein said at least one adenoviral E1 protein comprises an E1A protein [or a functional homologue, fragment and/or derivative thereof].